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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/084,676

02/28/2002

Iris Ziegler

148/50932

2539

23911

7590

04/13/2005

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 04/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/084,676	ZIEGLER ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, Dr. Ziegler's declaration under 37 CFR 1.132, request for reconsideration, all filed 12/15/04. Claims 17 and 38 are pending.

Claim Rejections - 35 USC § 102

1. Claim 17 remain rejected under 35 U.S.C. 102(e) as being anticipated by Mauskop (US 5,914,129).

Applicants state that a reference that discloses a mixture of diclofenac sodium and tramadol hydrochloride does not anticipate claim 17. Furthermore, applicants state that as per Dr. Ziegler's declaration, the release profile of tramadol hydrochloride and diclofenac sodium from pellets containing a compound of the two active substances (Test I) differs from the release profile from pellets formed only with tramadol hydrochloride (Test II) and from pellets formed only with diclofenac sodium (Test III) (page 4 of applicants' remarks).

2. Applicants' arguments filed 12/15/04 have been fully considered but they are not persuasive.

A compound of tramadol hydrochloride and diclofenac sodium reads on a mixture of or mixture that contains tramadol hydrochloride and diclofenac sodium. Ziegler's declaration does not compare the release profile of tramadol hydrochloride and diclofenac sodium from pellets containing a compound of the two active substances (instant claim 1) with release profile of a mixture of tramadol hydrochloride and diclofenac sodium as disclosed by Mauskop. The declaration describes Test 1, which is the instant claims, as homogeneously mixing tramadol and

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diclofenac and microcrystalline cellulose; and then granulating the mixture in the presence of water for moistening.

Claim Rejections - 35 USC § 103

3. Claim 38 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mauskop (US 5,914,129).

Applicants argue that Mauskop does not disclose or suggest the mixing and moistening steps as recited in claim 38 and that the prior art does not suggest that repeating the mixing and moistening step would be of any use. Furthermore, applicants state that even if the skilled artisan contemplated the repeated mixing and moistening steps, “such a person would conclude that these steps would provide no additional benefit and, more significantly, would increase the cost of production,” and that without a perception that the additional steps would somehow be of benefit, the skilled artisan would have no motivation to even try such a step. Applicants further argue that the skilled artisan would be discouraged from trying the steps if the additional steps would increase the cost for the production of the pharmaceutical. Also, applicants argue that the instant claim requires “formulating the mixture under energy input,” while the compressing and granulating process taught in Remington simply requires energy input and that the Office action does not explain how the Remington method amounts to formulating a mixture under an energy input. Applicants further state that compressing is typically used to form a tablet rather than to form a mixture and a mixture is achieved before any compressing step and that the Office action does not indicate how the methods taught in Remington could be used to arrive at a method comparable to the method of claim 38. That combining the Remington teaching with Mauskop

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does not teach the instant method, does not teach each and every element of the claim and that there is no motivation to modify the combined teachings of the references.

4. Applicants' arguments filed 12/15/04 have been fully considered but they are not persuasive.

Remington is relied upon as a teaching reference for known process in the art. In general, the process of mixing requires some energy form, either by stirring, or just mixing. Energy input requires some involvement of energy as when a mixture is formed, stirring, swirling or simple mixing requires some application of energy or energy is inputted to affect the mixing process. The oral formulation of Mauskop is discrete units such as capsules, cachets or tablets, or granules. The instant claim 38 is a process that involves mixing and any process where two components are combined requires the mixing of the two components. Regarding the issue of the added cost for the production, it is noted that applicants provided no cost amounts for a formulation that is formed by mixing without repeated process of mixing and one that is formed with repeated mixing step. The number of times mixing is repeated may be arbitrary by the skilled artisan since the mixing process ensures that the components are brought into intimate contact with each other by the mixing process. The cost for repeated mixing and moistening was not considered by applicants in the claims and by the prior art and the skilled artisan is capable of determine how many times the mixing and moistening would be done to effect adequate mixing of the components of the formulation in order to produce the oral formulation.

Double Patenting

5. Claim 17 remains provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 11 of copending Application No. 10/016.

Applicant argues that the co-pending claims require that active agents be in separate units while the instant claims requires that the active agents be formulated into a compound.

6. Applicants' arguments filed 12/15/04 have been fully considered but they are not persuasive.

The co-pending claims do not exclude compound formation and the instant claim does not exclude separate subunits.

Dr. Ziegler's declaration:

Examiner has considered the declaration. However, Test II and Test III are individual formulations of tramadol hydrochloride and diclofenac sodium respectively. The declaration does not provide comparison for Test IO and the formulation of Mauskop, which is a mixture of tramadol hydrochloride and diclofenac sodium.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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